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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,832	07/10/2000	SUZANNE CORY	017227/0159	3471

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FOLEY AND LARDNER
SUITE 500
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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/04/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,832

Applicant(s)

CORY ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 15-22, 28-30 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 15-20, 29, 30 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 21, and 22 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 6-9, 15-22, 28-30, and 36 are pending.

Claims 15-20, 29, 30, and 36 remain withdrawn from further consideration for the reasons given in the previous Office action (mailed on 08-23-2002).

Claims 6-9, 21, 22, and 28 are examined.

Specification

The objection of claims of record is withdrawn because the amended claims are no longer drawn to multiple inventions. The objection of the specification due to an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of the amendment. The objection of the disclosure at page 63, lines 13 and 14 is withdrawn in view of the amendment.

Claim 21 is **newly objected** to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The full scope of claim 21 is broader than the base claim because the nucleic acid molecules of claim 21 are not necessarily limited to at least 45 % identity to SEQ ID NO:9. Note there is no maximum limit of amino acids change in the polypeptides encoded by the instantly claimed nucleic acid molecules ("variant of an isolated nucleic acid molecules as claimed in claim 6).

Claim Rejections - 35 USC § 112

Claims 7-9 **remain rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Any other previous rejection not repeated is withdrawn in view of amendment.

The amended claim 7 recites "under moderate stringency conditions" but it is not clear what the metes and bounds are for the term. The term " under moderate stringency conditions" is not defined by the claim or the specification. What will hybridize depends on the conditions but the paragraph bridging pages 21 and 22 of the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The dependent claims are also rejected because they depend on the rejected claim.

Claim 9 says "An isolated nucleic acid molecules according to claim 7 of SEQ ID NO:9" but it is not clear what the metes and bounds are. If the scope of the claim is limited to SEQ ID NO:9, then amending the claim "an isolated nucleic acid molecule of claim 7 comprising SEQ ID NO:9" would obviate the rejection. For the purpose of this Office Action, the Office will assume that the scope of the claim is limited to SEQ ID NO:9. However, this treatment does not relieve applicant the burden of responding to this Office's Action.

Claims 6-8, 21, and 22 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a genus of isolated nucleic acid molecules comprising said molecules encoding proteins having at least 45 % identity to SEQ ID NO: 10 encoded by SEQ ID NO:9 (claim 6), nucleic acid molecules capable of hybridizing SEQ ID NO:9 under moderate stringency conditions (claim 7), said hybridizing molecules but also encodes proteins at least 45 % identity to SEQ ID NO: 10 (claim 8), variants of nucleic acid molecules as claimed in claim 6 where said variants encode proteins with at least one different amino acid different without maximum limit specified (claims 21 and 22), wherein said proteins are capable of inducing apoptosis.

Applicant argues, at page 6 last two paragraphs, pages 9-10 of the amendment that the specification provides several murine and human Bim proteins capable of inducing apoptosis including human BimEL, BH3 domain is important for apoptosis, and a variant of BimEL incapable of binding to dynein light chain has more apoptotic activity, and assay for functionality. These argument have been fully considered but found unpersuasive because the specification fails to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties,

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functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification does not provide the identification of the necessary 45 % identical structure of SEQ ID NO:10 that must be conserved in order to retain the recited functionality. Accordingly, in the absence of sufficient recitation of distinguishing identifying structural characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleotides, given that the specification has only described only human and mouse Bim cDNAs. Therefore, mouse and human sequences, not the full breadth of the claims, do not meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115). A definition by function with only 45 % sequence identity “does not suffice, to sufficiently describe a coding sequence of other nucleic acids homologs from as dog, cat, etc. (note page 4 line 25, where it says “a derivative of homologue” to instant SEQ ID NO:9 is envisioned as applicant’s invention) because it is only an indication of what the gene does, rather than what it is.” *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406.

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Claims 21, 22 remain rejected for reason of record and claims 6-8 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims rejection not repeated here is withdrawn. Applicant argues that certain mutants incapable of binding dynein have higher apoptotic activity and the specification teaches BH3 is important for apoptosis. These arguments are not commensurate in scope of the claims because those mutants are only one or two amino acid changes out of 198 amino acids BimEL protein, which is about 1 % sequence differences from SEQ ID NO:10. The specification fails to teach how to make 45 % sequence identity and/or hybridizing molecules encoding proteins that induce apoptosis.

Claim Rejections - 35 USC § 101

The rejection of the claims under 35 U.S.C. 101 is withdrawn because applicant amended the claims by adding "isolated".

Claim Rejections - 35 USC § 102

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Oltvai et al (27 August 1993, Cell 74, 609-619) is **now applied to claims 21 and 22.**

Applicant argues that the art does not teach the recited sequences in the amended claims but this argument is not persuasive because the instant claims are not limited to the recited sequences. See the claims objection above for further explanation.

Allowable Subject Matter

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

November 1, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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